(12) UK Patent Application (19) GB (11) 2 318 295 (13) A

(43) Date of A Publication 22.04.1998

(21) Application No 9621622.1

(22) Date of Filing 17.10.1996

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(51) INT CL^6
A61B 17/068

(52) UK CL (Edition P)
A5R RESC

(56) Documents Cited
WO 94/21181 A1 US 4493322 A

(58) Field of Search
UK CL (Edition O) A5R REL RESB RESC RESX
INT CL^6 A61B 17/068 17/072 17/115
ONLINE: WPI

(54) Wire-guided surgical stapler for closure of a puncture site in a blood vessel

(57) A surgical stapler comprises shaft 6 with a hollow channel running throughout its length. A surgical staple is housed in the distal end of said channel and a push rod system runs along the shaft to advance and deploy the staple. The stapler is brought into position at puncture site 14 over guide wire 1 which has previously been inserted into blood vessel 5 through puncture 14. Correct placement of the stapler is confirmed by advancing tube 2 over guidewire 1 into blood vessel 5 through puncture 14 when backflow of blood will be observed. Following withdrawal of tube 2, the staple is deployed into artery walls 9 and the stapler removed over guidewire 1 which itself is removed when haemostasis is observed.

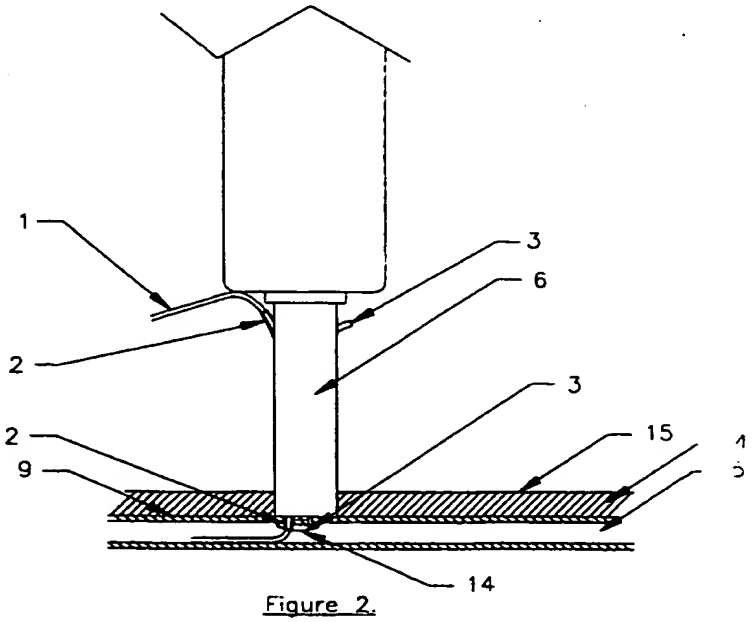

Figure 2.

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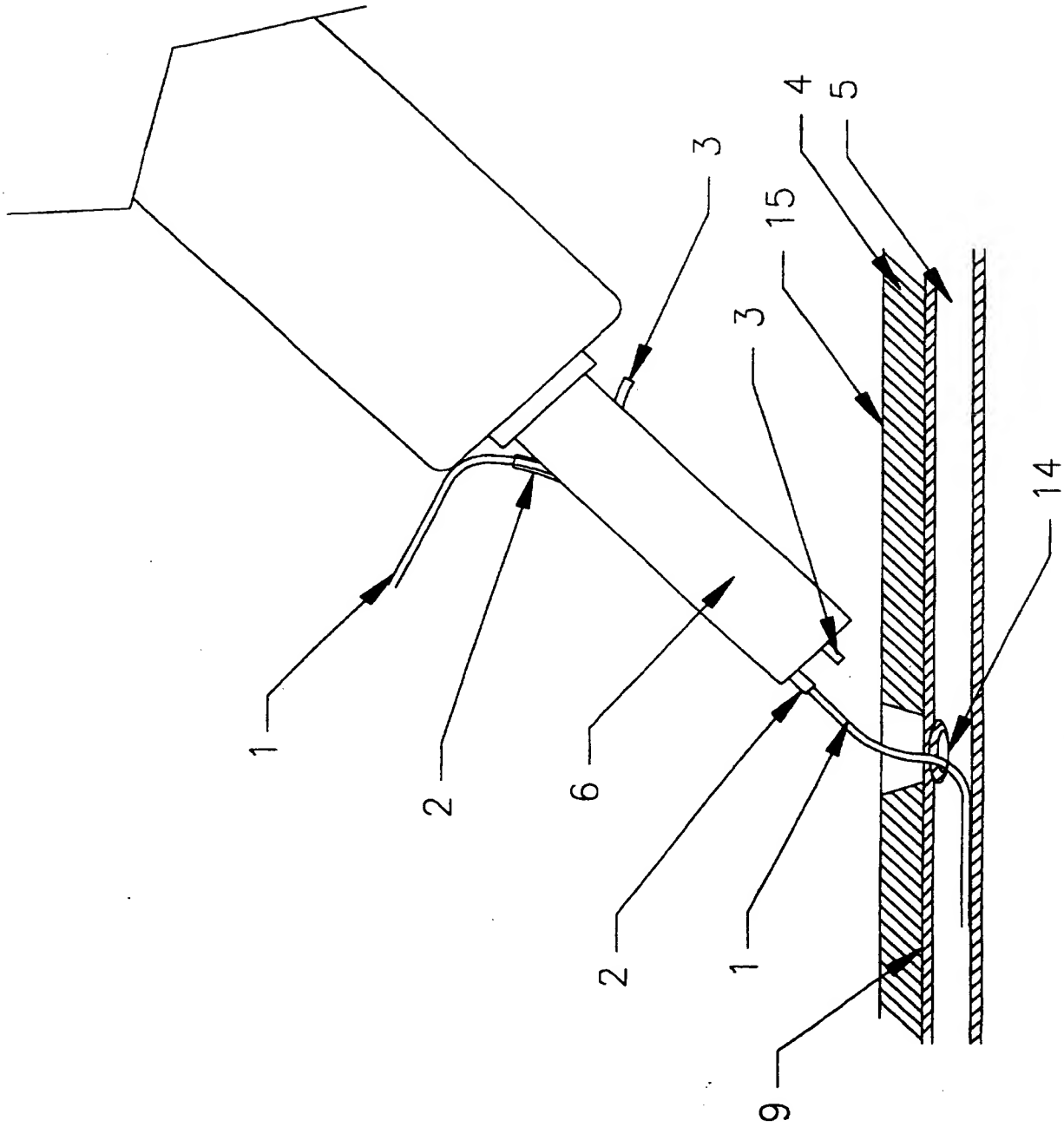

Figure 1.

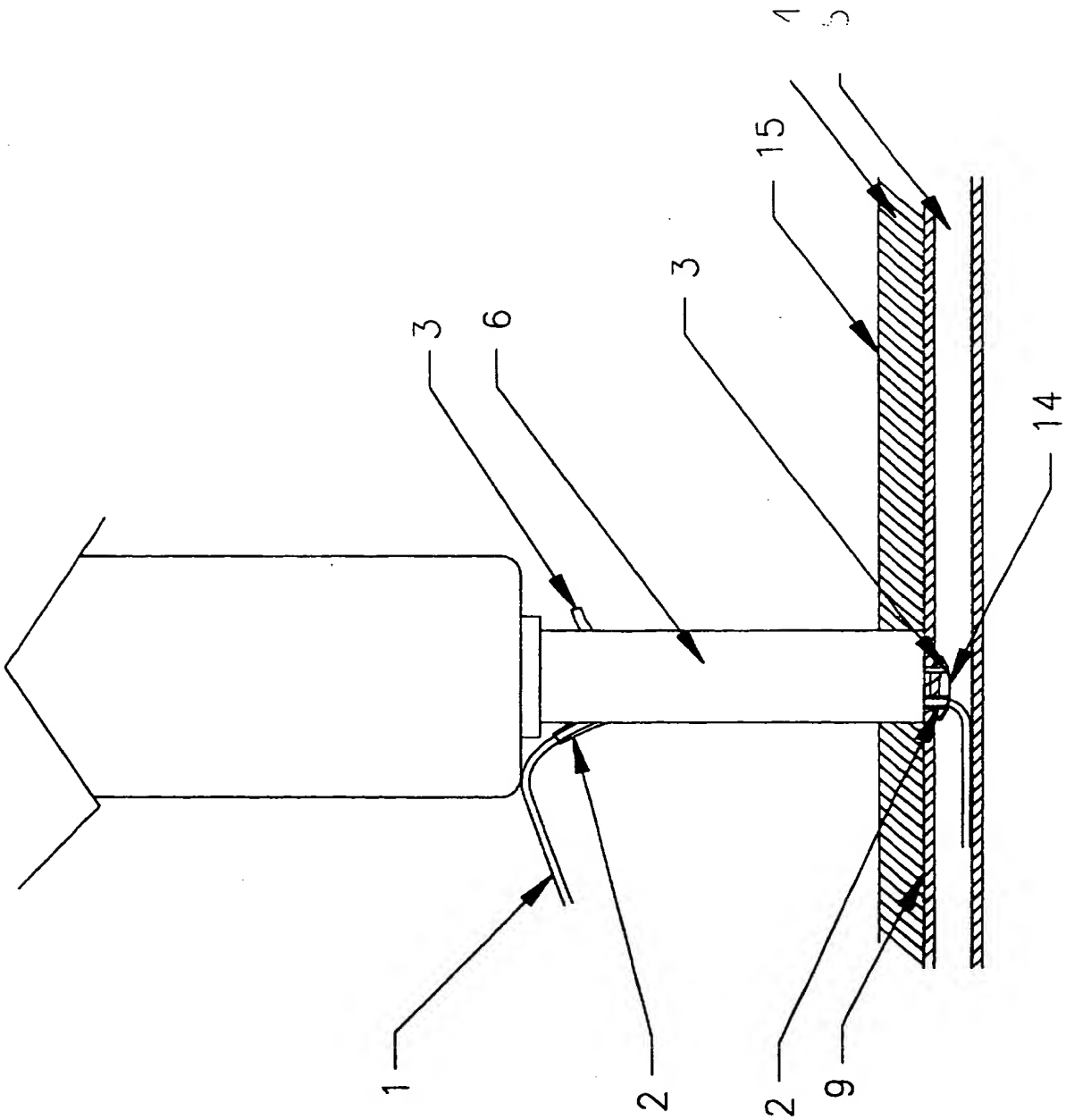

Figure 2.

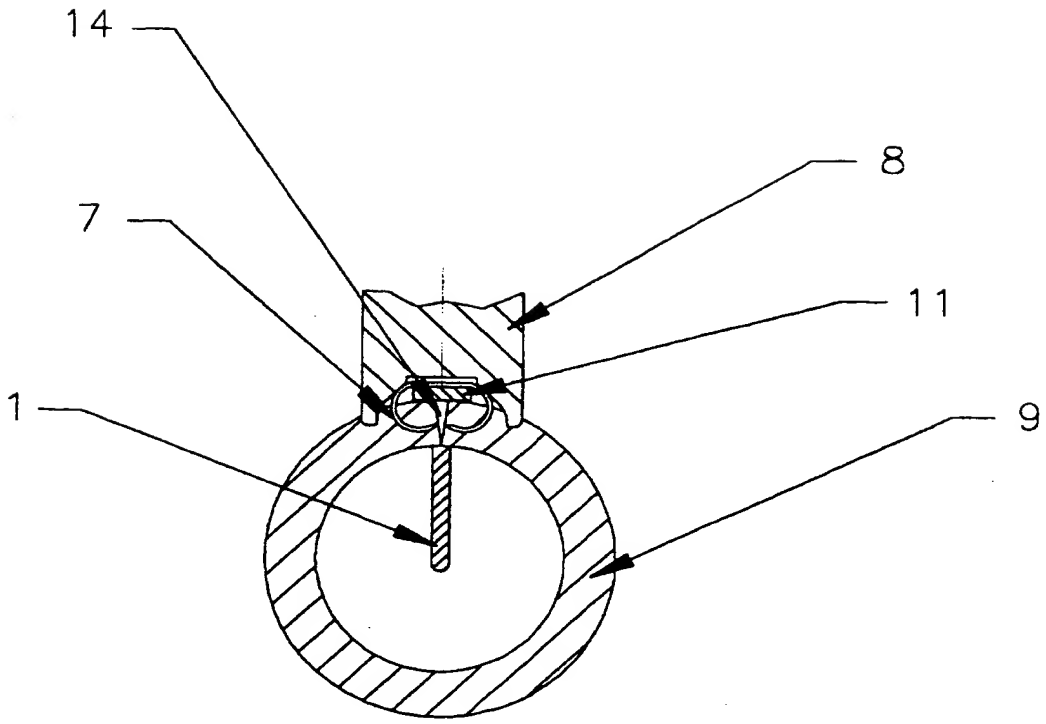

Figure 3.

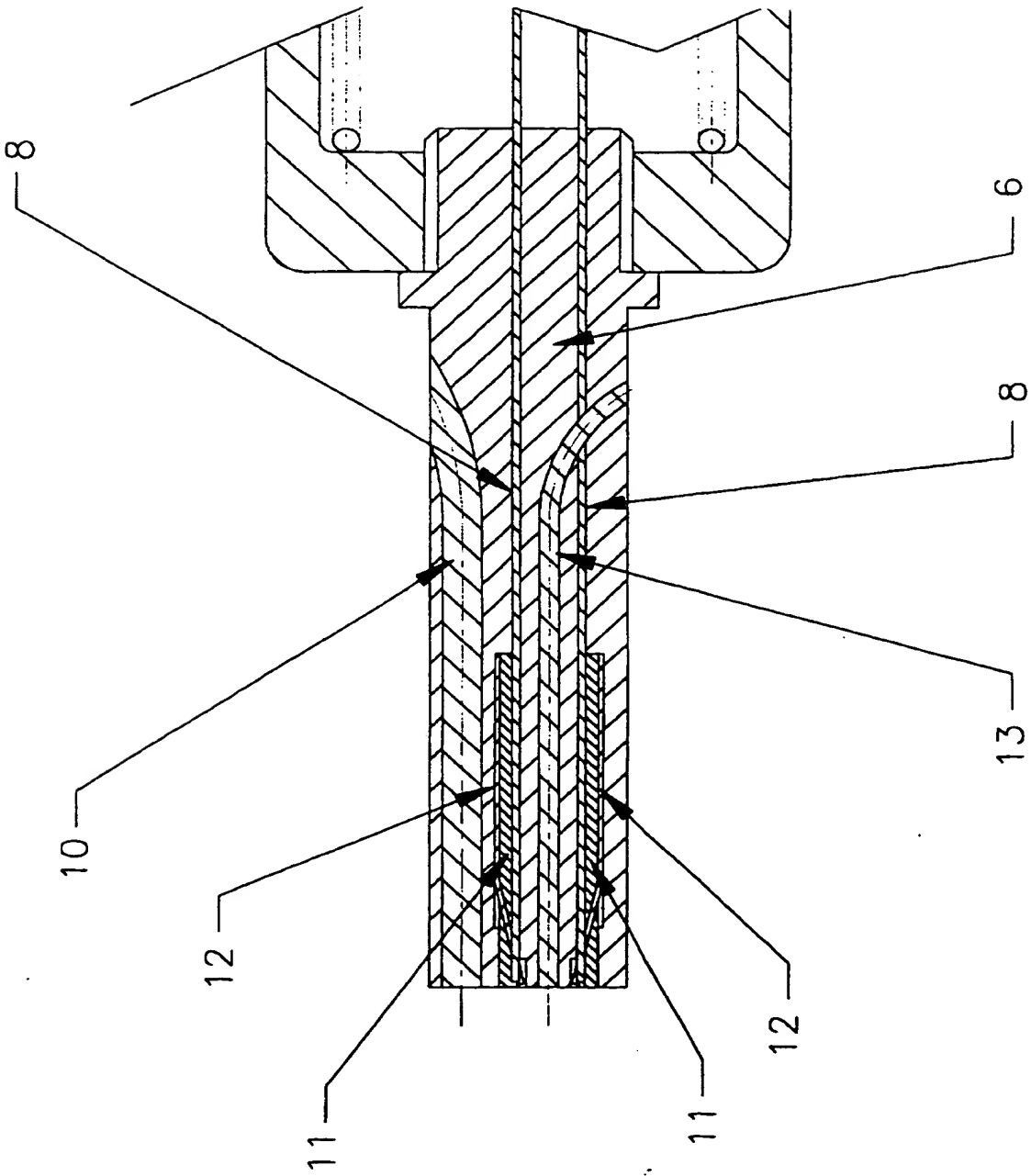

Figure 4.

Device and method for percutaneous closure of a vascular puncture site

Field of Invention

The present invention relates to a device for sealing a puncture wound in a blood vessel and the related method employed to accurately localise the blood vessel puncture site using the device in order to effect satisfactory closure of puncture by using said device.

Related Background

An ever increasing number of vascular interventional procedures are being undertaken by cardiologists and radiologists. With the growing use of both diagnostic and therapeutic procedures requiring percutaneous vascular access, a real demand exists for a method and device for closing the puncture site in the blood vessel post interventional procedure.

Due to ease of access, the most common site selected for these percutaneous arterial interventional procedures is the femoral artery. The normal procedure is to insert an angiographic needle into the femoral artery. This is followed by the insertion of a guide wire and over this guide wire successive dilators are passed percutaneously into the artery in order to widen the puncture in the artery sufficiently to allow the sheath of optimal diameter for the diagnostic or therapeutic procedure to be inserted. Through this sheath is then inserted the required catheter or interventional device in order to perform the required diagnostic or therapeutic procedure on the patient.

The invention of the method and device for closure of a blood vessel puncture described here are independent of the type of catheter or other interventional devices used for the treatment of a patient. Furthermore the device employed for the modalities of either diagnosis or therapeutic intervention will hereafter be

referred to in the very broad sense as "catheters", but of course will cover any device which is inserted into a blood vessel of the body.

Furthermore the subject of the invention is independent of the blood vessel involved which may be located anywhere in the body and may also include venous structures.

The physician carrying out the diagnostic or interventional procedure would ideally choose to use the largest sheath possible. However at the end of the procedure this sheath requires to be removed and the standard treatment on removal of the sheath involves digital pressure on the artery, supplemented with external compression such as sandbags, pneumatic extension cuffs, or adjustable vice-like devices which may be graduated to apply different degrees of pressure on the skin over the puncture site. This method results in the occlusion of the puncture site by thrombosis of blood in the wall of the puncture site and haemostasis in the percutaneous tract. This procedure results in considerable discomfort for the patient and is associated with a long period of immobilisation. Also the occurrence of unpredictable post-procedural haemorrhaging during time periods varying from hours to days after the intervention are not uncommon. These post procedural bleeds result in considerable morbidity and may even be fatal for the patient. The additional healthcare cost in dealing with this complication may be considerable and any method or device which can be invented to reduce these problems would offer a preferable option for closure of the puncture site by the cardiologist or radiologist.

A series of devices have been invented to address some of these problems. (A). Datascope Corp. USA, (B). PerClose Corp. USA, (C). Kensey Nash Corp. USA, (D). Bard Corp. USA.

(A) The Datascope Corp. USA patents relate to the dilation of the percutaneous tract from the outer skin to the blood vessel puncture site and packing this tract

with collagen material in order to effect a tamponade effect on the vessel puncture site.

(B) The Perclose Corp. USA patent describes a device involving the insertion of a suture applying device comprising a shaft which carries a pair of needles near its distal end. The needles are joined by a length of suture and the shaft is used to introduce the needles into the lumen of a body structure and push the needles back through the tissue on either side of the puncture site. After the needles have passed through the tissue, they are captured on the shaft and drawn outwards through the tract leaving a loop of suture behind to close the puncture site near the body lumen. The suture can then be tied and pushed back through the tract to complete the closure.

(C) The Kensey Nash Corp. USA patents describe a puncture seal device for stemming the flow of blood from a punctured blood vessel by delivering an absorbable plug inside the lumen of the blood vessel. This absorbable plug is joined to a pledget of collagen outside the lumen of blood vessel by means of an absorbable suture. A device is described which compresses the outer collagen pledget against the outer blood vessel wall while simultaneously compressing the inner absorbable plug against the inner side of the blood vessel wall resulting in the stemming of haemorrhage from the puncture site.

(D) The Bard Corp. USA Fem Stop patents relate to the pneumatic compression of the puncture site and relies on this compression to facilitate thrombosis of the blood in the puncture site and percutaneous tract resulting in haemostasis.

The present invention here described discloses a new method and a new device for sealing a blood vessel wall puncture by approximating the walls of the punctured blood vessel in such a way as to obliterate the puncture site. The present invention will also find use in other medical procedures which rely on percutaneous access to hollow organs such as laparoscopic procedures,

arthroscopic procedures, and the like. It will also find use in closing body orifices approached directly by the device or approached through body cavities or origans.

General Description of Device and Method of Use

The method of choice for sealing a blood vessel puncture following a diagnostic or interventional procedure using the puncture site for vascular access is to approximate the walls of the puncture site. This ideal closure may be achieved following the placement of vascular sutures across the puncture site and subsequently tying these sutures in a manner so as to cause approximation of the opposite walls of the punctured blood vessel. While such a method has been described using a percutaneous technique, it is not without its problems and a more straightforward mechanical method of achieving puncture closure would be preferable for the physician. With this in mind a mechanical stapling device and a method for its use has been invented which will allow the operator to mechanically occlude the puncture site in an effective and reliable manner following removal of the sheath

Prior to the removal of the sheath from the blood vessel, a guide wire is inserted into the blood vessel via the sheath. This guide wire may have incremental marking measurement scale along its length, allowing the operator to estimate precisely the amount of guide wire which is placed within the blood vessel. After removing the sheath, should it prove necessary, serial dilators may be placed over the guide wire and used to dilate the subcutaneous tract down to the level of the external wall of the arterial puncture. The dilator may contain a radio-opaque marker and also a measurement scale which allows the accurate measurement of the length of the percutaneous tract from the skin level to the outer surface of the blood vessel puncture site. The dilator may have a fine bore plastic tube running through its length which passes over the guidewire. The calibre of this plastic tubing is such that it will be sufficiently small to pass into the blood vessel. This

tubing may be fixed to the dilator and protrudes for approximately 2-4mm beyond the distal end of the tissue tract dilator. Therefore when blood is observed pulsating back from the distal end of this tubing on to the skin, it can be taken to signify that the dilator has reached the outer surface of the blood vessel. When this occurs, the exact depth of the percutaneous tract may be measured. Transmission of pulsation of artery via dilator to operator may be taken as further evidence that the dilator is resting against the outer wall of artery. After completion of dilation of the tract, the dilator is removed over the guidewire which itself is left in place.

A new vascular stapling device is now advanced over the guidewire **1 (See FIG. 1).** The shaft of the stapling device which may be rigid or flexible slides down along the guidewire through the dilated subcutaneous tissue **4** tract and rests on the wall of the blood vessel **9** . The shaft **6** of the stapling device may be calibrated in order to confirm to the operator that the previously measured length of the tract has been travelled by the shaft. Running through the shaft of the stapling device may be one or two blood vessel puncture site locating plastic tubes **2, 3** which may be advanced over a guidewire **1** . These tubes may be located in the front and/or behind and/or beside the one or more staples to be delivered to close the puncture site. This plastic tubing may be calibrated and its exact relationship with the tip of the stapling device is known because of calibrated graduated measured markings or other method of marking along its length. In addition this tubing may be radiopaque further facilitating identifing its position in relation to the puncture site.

As the distal end of the stapling device which is advanced over a guide **1** comes to lie on the blood vessel **9** , an approximate 4mm protrusion of the blood vessel puncture site locator plastic tubing **2, 3** may enter over the guide through the puncture site **14** into the lumen of the blood vessel **5** . Pulsating blood will then traverse back through the tubing, through the shaft **6** of the stapling device, and out through the proximal lumen of the tubing **2, 3** . This can be taken as an indication that the tip of the stapling device rests against the outer blood vessel wall 9 at the

puncture site **14** . Transmission of a pulsating feeling from artery via stapler to operator may be taken as further evidence that the stapler is resting against the outer wall of the artery. Also a second plastic tubing **3** which may be located behind the first or second staple may be advanced into the arterial puncture to confirm exact localization and alignment of the stapler if so desired.

Following confirmation of the stapler position, the blood vessel locator tubing **2, 3** may be pulled back along the guide wire **1** into the shaft of the stapler. The pulsation of blood then ceases. At this point the distal of the stapler which is orientated by the guidewire is now placed firmly against the blood vessel wall **9** . If the shaft **6** of the stapling device is brought towards perpendicular position **(See FIG. 2)** in relation to the skin **15** , it will result in the guidewire assuming an angle approaching or greater than 90 Degrees and this may cause the puncture hole to be stretched and to change from a roundlike shape to resemble more a vertical opening and therefore has the effect of bringing the opposite walls closer together. The sensation of the pulsating artery may be transmitted along the stapling device and may help to further confirm position. A safety latch on the handle of the stapler may be released and graduated pressure is applied to the handle of the stapler which results in the 2 needle sharp legs **(See FIG. 3)** of one or more separate staples placed in parallel to be deployed simultaneously (or consecutively if delivery mechanism so designed) in order to engage the blood vessel wall. In the case where two staples are delivered, the four staple points (2 points per staple) are ejected either in the longitudinal or transverse axis (if stapler is rotated 90 degrees) of the blood vessel and their accurate positioning is assisted by the previous measurements described above and by the fact that the staple delivery system is held on a guide wire. The one or more pre-formed staples may be totally deployed into the wall of the blood vessel **9** while at the same time undergoing a predetermined deformation **7** as defined by the shape of the staple former **8** mechanism in the stapler head.

If required, an angiogram may be performed via a side arm on the plastic tubing

which traverses the length of the stapling shaft. Contrast medium may be injected into the blood vessel, provided the tubing is advanced along the guide wire and into the blood vessel. Alternatively, the contrast medium may be injected at the outer surface of the blood vessel if so desired in order to reconfirm the exact positioning of staples. Also a radio opaque marker may be present in the tip and shaft of the stapling device and this combined with the radio opaque nature of the staples themselves may facilitate further confirmation that the desired placement has taken place. Once this is confirmed, the fine bore tubing may once again be retracted if it has been advanced.

The trigger mechanism which advances the single or double staple pushers (which are part of the staple former mechanism **8**) **(See FIG. 4)** may be further advanced and this results in one or both staples being further deformed to the desired shape and ejected by the formed staple unload spring **12** from the distal end of the stapler simultaneously (or consecutively if staper so designed), with the transverse member of each staple perpendicular to the long axis of the blood vessel. Alternatively, they may be discharged in parallel to the long axis of the blood vessel resulting in a transverse closure of the puncture site. Closure of the staples will result in the approximation of the opposite walls of the puncture site. The end result will be a minimum of one staple (preferably two) closing the puncture site by means of deformation of two metal or absorbable staples (or staples made from other nonabsorbable implantable material) in such a way as to approximate the walls of the puncture site.

During the final closing action of the staples, the operator may decide whether or not to close the puncture site around the guide wire. As previously discussed the guide wire will be of sufficiently fine calibre so as to result in minimal subsequent problems of bleeding on its removal. The operator may find it desirable to leave the guide wire in place after deployment of the staple or staples if he believes that there is a danger that the vascular procedure which has been carried out will require a re-intervention within a defined time period. If however, the operator is

confident that no subsequent intervention in the immediate post-procedure period will be warranted, the guide wire may be removed prior to the final formation of the staple resulting in the closure of the puncture site. Alternatively the total procedure of deployment, deformation and ejection of the staple or staples from the stapling device may be carried out in one continuous movement over the guidewire which may be removed immediately after deployment.

Two spring-like or other mechanisms **12** will eject the staples either towards the midline of the stapler shaft or towards the lateral walls of the stapler when the final trigger activation squeeze mechanism has been completed. This will result in releasing the staples from the distal end of the stapler and allow withdrawal of the stapler shaft from the percutaneous tract over the guide (unless guide previously removed) with ease.

Haemostasis of the puncture wound having been achieved, the tract itself is now inspected for any subsequent signs of local bleeding. Tract haemostasis is usually achieved by application of a wound pad. If the operator so desires, other absorbable packing material such as collagen, calcium alginate, oxidised cellulose or cellulose gel may be used to plug the tract. However, this step is generally not necessary and is at the discretion of the operator.

Overview of Invention of Device

Here described is a method and device for arresting the flow of blood from a blood vessel puncture site after completion of a percutaneous medical procedure where said procedure results in the insertion of a sheath along a guide wire into the lumen of the patient's blood vessel through a puncture in the patient's skin and through the underlying subcutaneous tissue into the artery,

The invention of this device relates to a mechanical means which can be used to close a puncture in a blood vessel wall. Such a puncture may result from certain procedures such as angiography, percutaneous transluminal angioplasty, or insertion of an intra-aortic balloon pump or vascular stent. Generally a guide wire is inserted into an artery or vein via a hollow needle. Over this guide wire a dilator and sheath are placed into the blood vessel, most frequently the common femoral artery in the groin area of the patient's leg. When the interventional or diagnostic procedure has been completed, the sheath through which the procedure has been performed must be removed and the puncture site closed. In accordance with this invention, puncture wounds of this type are closed by applying a mechanical surgical staple (or staples in parallel) preferably with the transverse member of the staple perpendicular (but may be at any angle) to the longitudinal axis of the femoral artery. When the staple or staples are deployed, they pierce the outside of the arterial wall. The stapling device itself has been brought into place over a guidewire. The staple or staples which may be metal or made of absorbable polymer are deformed in a shape similar to a C or B as they pass through and approximate the opposite walls of the blood vessel about the guide wire.

An apparatus is disclosed for the percutaneous application of surgical staples to a vascular puncture site in order to close the puncture site.
The apparatus includes a frame, and a generally elongated shaft section which may be flexible connected to the frame and extending distally there from. The apparatus has one or two hollow channels throughout a length (at least slightly longer than the depth of the percutaneous tract from the outer skin to the outer surface of the blood vessel) of the shaft which allows the stapling apparatus to be advanced over a guide, through the percutaneous subcutaneous tract and onto the surface of the blood vessel. The guide may be a guidewire which has been placed previously percutaneously into a blood vessel while performing a percutaneous intravascular procedure such as angioplasty or a vascular stent placement. A staple storage area exists in the distal end of the device which stores one, two or

more surgical staples at the distal end of the shaft section of the apparatus. The staples may be deployed simultaneously in parallel about the axis of the guidewire and each staple is capable of being configured and adapted in such a manner so as to close a wound puncture site on deformation. An elongated pusher system formed from several assembled components (including the staple former) and extending from the frame to the shaft section is provided for advancing all staples simultaneously into the outer wall of the blood vessel about the axis of the guide. The pusher system also includes a trigger mechanism to actuate the pusher. Staple forming and anvil means provide for closing the staple or staples in such a manner as to incompass the wall of the blood vessel by penetration of the staples into the outer wall of the blood vessel with subsequent deformation resulting in apposition of the opposite walls of the puncture hole.

Said method comprises insertion of a fine bore guide wire into the blood vessel, passing a dilator (if necessary) over said guide wire through the percutaneous tract and underlying subcutaneous tissue onto the outer surface of the blood vessel. The site of the dilator may be confirmed by advancing a fine bore tube through the lumen of the dilator over the guidewire and into the blood vessel for a fixed distance as indicated by graduated markers which may be present on both dilator and plastic tubing and also facilitated by radio opaque markers, which may be seen on radiological screening.

Following removal of said dilator and plastic tubing and placing guide wire through channel running along shaft of surgical stapling device, said surgical stapling device is advanced along the guide wire through the skin and underlying tissue onto the surface of the blood vessel. Localisation of distal end of stapler may be facilitated by graduated markings on side of stapler shaft. Position may be confirmed by advancing inner blood vessel locator tubing along shaft of stapler on guide wire and into the puncture site. Tubing may be advanced into the blood vessel lumen for fixed length, and exact position of distal end of stapler with relation to outer surface of blood vessel may be confirmed by observing the

backflow of blood. The ability exists to perform angiogram through plastic tubing if required. On retracting plastic tubing into shaft of stapler and initiating deployment of the staples simultaneously and in parallel (if more than one staple is deployed), the ability may exist to observe indirectly the deformation phase of the staples on a diagrammatic marker within handle or body of stapler. The ability also exists to observe protrusion of vertical legs of each staple on radiological screening if required. The ability also exists to inject contrast medium around surface of blood vessel to confirm positioning if required. Further activation of the staple delivery mechanism results in advancing staples of pre-determined shape onto pre-determined shaped anvil. At any stage the guide wire may be removed from the blood vessel, even before staples have engaged in outer surface of arterial wall.

The closure mechanism of staples is completed via advancing staple formers which force staples into the arterial wall on one side of the guide wire (if only one guide wire is used) in a vertical manner and deform in a predetermined shape which will cause the opposite sides of puncture hole to approximate. The puncture hole will assume a longitudinal or transverse closure or a hybrid of both. The stapler may be withdrawn along the guide wire (if still in place) once trigger mechanism has been totally closed. The stapling device, following advancement over a guidewire, has the ability to release one or more of the staples in parallel from the distal end of the delivery device, at the end of the firing cycle. Also, the ability may exist to mechanically maintain each step in the firing cycle in a fixed position until further pressure is applied on trigger. This ensures smooth and controlled delivery of staples to margins of puncture site and should result in satisfactory closure of same.

Detailed Description of Specific Embodiments of Device

When the interventional or diagnostic procedure has been completed a guide wire **1** is generally left in place which passes through the percutaneous tract and via the

puncture site **14** into the lumen of the blood vessel **5 (See FIG. 1)** . In the first instance, this guide wire may be exchanged in the normal manner for a fine bore guidewire which may have radio-opaque markers along its length which will signify its exact site in relation to the puncture site and to the mechanical stapling device which will be advanced over the guide wire.

With the guide wire in place, if required, a dilator with a diameter equivalent to that of the stapling device shaft may be advanced over the guide wire and into the percutaneous tract in order to dilate and localise the length of tract and depth of blood vessel with relation to skin surface. This dilator may have a hollow channel which contains a fine bore plastic tube. This slideable length of fine bore plastic tubing may accommodate a guidewire while also acting as a blood vessel puncture locator. The site of the puncture is indicated when blood vessel has been entered and is indirectly identified by means of back-flow of pulsating blood. This slidable tubing may have graduated markings which will allow its tip to be accurately located at all times with respect to the proximal end of the dilator. When the dilator reaches the surface of the blood vessel, its position may be confirmed by advancing the plastic tubing approximately 4mms along the guidewire through the puncture site and into the blood vessel. This will result in a backflow of blood through the tubing and subsequent confirmation of the position of dilator and depth of percutaneous tract. Following confirmation, the tubing may be retracted along guide wire and then the dilator may be removed. The dilator itself may have radio opaque markers along its length which can be located at any time via radiological screening if required. Also a side port on the plastic slideable tubing which passes through the length of the dilator may allow an angiogram to be performed confirming the tip of the plastic tubing within the blood vessel lumen and hence the accurate localisation of the tip of the dilator against the blood vessel wall. Alternatively, the dilator may be constructed in such a manner such that it has a central channel and its distal end narrows for the last portion to a size slightly larger than the guidewire. This design facilitates dilation of the tract and localization of the puncture site. Alternatively the shaft **6 (See FIG. 2)** of the stapling device

may be used as a tissue tract dilator because it may have all the embodiments described as features of the tissue tract dilator as described above.

Following removal of the dilator, the stapling device may now be advanced along the guidewire and onto the surface of the blood vessel. The stapling device consists of a distal nose section housing a minimum of one metal or absorbable or nonabsorbable implantable staple, but preferably two, set in parallel which may be deployed simultaneously while the stapler is positioned over the guide wire. Within the distal nose section of the stapling device, these staples may come into contact with push rods (of which the staple formers **8** may be part) which traverse the length of the shaft of the stapler. Furthermore the shaft **6** of the stapler may be of sufficient length to allow deployment of the staples by the operator while simultaneously carrying out radiological screening if so desired. This may involve injecting contrast medium into the artery via tubing in the stapler shaft while simultaneously deploying the staples in order to confirm to the operator the exact position of the staples.

The apparatus comprises a frame and shaft (which may be flexible) **6** which stores at least one surgical staple at its distal portion. The shaft has at least one purposely built hollow channel **10, 13 (See FIG. 4)** running throughout its length which allows the shaft **6** to be advanced over a guide **1** which has previously been placed percutaneously into a blood vessel lumen **5** in order to secure vascular access as previously described for percutaneous intravascular interventions. This purposely built channel (or channels) **10, 13** may also be used to advance blood vessel puncture site locator tubing **2, 3** along guidewire or by itself into blood vessel puncture site **14** . The frame and shaft (which has been advanced over the guidewire) house a staple pushing apparatus (of which the staple forming mechanism **8** may be a part) which advances the staple or staples into the margins of the puncture site on the outer surface of the blood vessel **(See FIG. 3)** . At the distal end of the shaft may be an anvil **11** means for closing the staple in a manner that causes the staple to penetrate the wall **9** of the blood vessel. Subsequent

deformation of the staple about the anvil **11** will result in the apposition of the opposite walls of the puncture site. The staple advancing system (of which the staple former **8** may be a part) may extend from the frame through the shaft **6** of the device and may be activated by a trigger mechanism attached to the frame and forming a part there of.

The surgical staple or staples may be stored in parallel beside each other with the possibility for a guide to pass on a track **10, 13** between them (or in front or behind them) may exist in the case of an instrument housing two staples at its distal end. In the case where a single staple is housed in the distal end of the stapler, the possibility may exist to pass a guide along the shaft of the stapler via a track **10, 13** and into the blood vessel lumen **5** via the puncture site **14** either in front or behind or on both sides (if more than one channel exists in shaft of stapler) of the mounted staple. The staples may be stored with the transverse member of the staple perpendicular to the longitudinal axis of the shaft. The shaft may be rotatable. This point of rotation may begin at the junction between the frame and the shaft. The distal end of the shaft may have a pivoting joint. Throughout the length of the shaft, at least one elongated rod may be positioned within the shaft to act as a pusher to deploy one or preferably two staples simultaneously or consecutively and in parallel while the the stapler is positioned over the guide. The means of advancing the staples distally may be controlled by the operator at a proximal location. The distal end of the staple former **8** engages the staple or staples and advances the staple or staples in the distal direction. The staple former which forms the distal end of the staple pusher has at its distal end a plate member, and the plate member may be dimensioned, configured and arranged to engage and advance the staple distally.The staple storage area at the distal end of the shaft includes at least one but preferably two anvils **11 (See FIG. 3)** which each engage a staple and deform it to a predetermined configuration. The staples may each be formed by a length of wire having two legs generally perpendicular or slightly angled to a transverse interconnecting bar. The staple former may have a means of two upstanding leg members which can engage a portion of the transverse bar of each staple when the staple is advanced distally by the plate

member of the staple member. The leg members of the anvils may be so configured such that they cause the legs and transverse bar of the staple to fold inwardly over the anvil. On completion of the staple closure, a resilient means **12** may be positioned below each staple which may result in each staple being lifted above the level of the anvil upon withdrawal of the staple advancing plate member. The means to advance the push rods and plate member of the staple former which engages the staples may be controlled to a rachet mechanism which may be connected to the frame of the apparatus. Advancment of the push rod and plate member may be achieved by a finger operated lever on the frame. The frame may have a pistol like shape and the trigger mechanism may be manually gripped by the operator. The shaft may be rotatable about the longitudinal axis of the frame and may have a hollow shaft throughout its length which allows the instrument to be advanced over a guide. Alternatively, contrast medium may be injected through a fine bore plastic tube which runs the length of the shaft of the apparatus and also may be advanced on a guide into the lumen of a blood vessel.

A surgical staple is adapted to oppose the opposite walls of a puncture site in a blood vessel . The staple may comprise of a length of wire and two perpendicular legs which are joined by a transverse member. These perpendicular legs are sharpened and will penetrate the outer wall of the blood vessel. Deformation of the bridge portion of the staple will result in both legs of the staple deforming in arcuate manner and facing in a direction generally towards the centre of the transverse wire portion. Deformation of the staples occurs over each anvil and results in the shortening of the transverse member which ultimately results in the opposite walls of the puncture site being advanced towards each other. The leg members of the staple are folded in such a manner so not to interfere with each other. The surgical staple may be made from stainless steel, titanium or any absorbable or non-absorbable implantable polymer. The closure mechanism will therefore result in the apposition of the opposite walls of the punctured blood vessel. These apposed walls may be slightly everted.

On completing the closure mechanism of the stapler handle, the indicator on the handle (if present) may show that the staple closure cycle is complete and on release of the handle, the deforming push rods may retract into the shaft of the stapler. This retraction movement of the push rods may cause a spring **12** or other mechanism on the side of the stapler shaft wall (which was deformed by the advancing staple former) to return to its original shape. This spring-back effect may result in one or both of the fully formed staples being ejected from their housing in the distal end of the stapler. Since the staples are now free of the stapling device nose, the staple device itself may now be easily removed from the percutaneous tract along the guide wire.

The procedure described above may be carried out using a kit comprising of a surgical staple, guide wire, fine bore plastic tubing for performing an angiogram and localising the position of blood vessel puncture site in relation to the stapler, a dilator with a hollow channel and graduated markings on its outer surface which can be detected radiologically, a connector side arm for the fine bore tubing through which saline or contrast medium may be injected. The apparatus and staples for the kit are constructed according to the invention. Components may be supplied as part of a kit or they may be supplied in a blister type or other packaging.

Brief description of the drawings

Preferred embodiments are described herein below with reference to the drawings;

Figure 1 is a schematic view of an apparatus constructed according to the present invention for applying a surgical staple about the axis of a guide to occlude a blood vessel wall puncture site.

Figure 2 is a schematic view of the surgical stapling device which has been

brought into position over a guide and its position may be indirectly confirmed by observing the back flow of blood through the blood vessel puncture site locator tubing.

Figure 3 is a cross sectional view with the guide wire still in place illustrating the mechanism at the distal end of the instrument for staple advancement, blood vessel penetration and staple deformation resulting in approximation of the opposite walls of the blood vessel puncture site.

Figure 4 is a schematic view in section of an apparatus constructed according to the present invention. In this view is seen the distal end of an instrument capable of deploying two staples simultaneously because two staple formers, two staple forming anvils and two formed staple unload springs have been incorporated into the design. Also seen are the two purposely incorporated channels which accomodate the blood vessel locator tubing and guide wires.

KEY TO REFERENCE NUMBERS ON FIGURE 1, FIGURE 2, FIGURE 3, FIGURE 4

1 Guide Wire
2 Blood Vessel Locator Tubing
3 Secondary Blood Vessel Locator Tubing
4 Subcutaneous Tissue
5 Lumen of Blood Vessel
6 Shaft of Stapling Instrument
7 Closed Staple
8 Staple Former
9 Artery Wall
10 Track to accomodate Arterial Puncture Site Locator Tubing and Guide Wire
11 Staple Forming Anvil

12 Formed Staple Unload Spring

13 Track to accomodate Secondary Arterial Puncture Site Locator Tubing and GuideWire

14 Blood Vessel Puncture Site

15 Skin of Patient

Summary

Here described is a method and device for arresting the flow of blood from a blood vessel puncture site after completion of a percutaneous medical procedure where said procedure results in the insertion of a sheath along a guide wire or other guiding mechanism into the lumen of the patient's blood vessel through a puncture in the patient's skin and through the underlying subcutaneous tissue into the blood vessel.

Said method comprises insertion of a guide wire or other guiding mechanism into the blood vessel through existing sheath at end of diagnostic or interventional procedure, passing a dilator over said guide wire through the percutaneous tract and underlying subcutaneous tissue onto the outer surface of the blood vessel. The site of the dilator may be confirmed by advancing a fine bore tube through the lumen of the dilator over the guidewire and into the blood vessel for a fixed distance as indicated by graduated markers which may be present on both dilator and plastic tubing and may also be facilitated by radio opaque markers, which may be seen on radiological screening.

Following removal of said dilator and plastic tubing and placing guide wire through channel running along shaft of surgical stapling device, said surgical stapling device is advanced along the guide wire through the skin and underlying tissue onto the surface of the blood vessel. Following confirmation of the stapler position, the tubing may be pulled back along the guide wire into the shaft of the stapler.

The pulsation of blood then ceases. Localisation of tip of stapler may be facilitated by graduated markings on side of stapler shaft. Position may be confirmed by advancing inner plastic tubing along shaft of stapler on guide wire and into the puncture site. Tubing may be advanced into the blood vessel lumen for fixed length, and exact position of distal end of stapler with relation to outer surface of blood vessel may be confirmed by observing the backflow of blood. The ability exists to perform angiogram through plastic tubing if required. At this point the distal of the stapler which is orientated by guide wire is now placed firmly against the blood vessel wall. If the shaft of the stapling device is brought towards perpendicular position in relation to the skin, it will result in the guidewire assuming an angle approaching or greater than 90 Degrees and this may cause the puncture hole to be stretched and to change from a roundlike shape to resemble more a straight line and therefore has the effect of bringing the opposite walls closer together.

On retracting plastic tubing into shaft of stapler, deployment of the staple or staples is initiated simultaneously and in parallel (if more than one staple is deployed), the ability may exist to observe indirectly the deformation phase of the staples on a diagramatic marker within handle or body of stapler. The ability also exists to observe protrusion of vertical legs of each staple on radiological screening if required. The ability also exists to inject contrast medium around surface of blood vessel to confirm positioning if required. Further activation of the staple delivery mechanism results in advancing the staple or staples of pre-determined shape onto pre-determined shaped anvil. At any stage the guide wire may be removed from the blood vessel, even before staples have engaged in outer surface of arterial wall.

The closure mechanism of staples is completed via advancing cams which force staple or staples into the arterial wall with the guide wire still in place in a vertical manner. Deformation of the staple or staples to a predetermined shape which will cause the opposite sides of puncture hole to approximate. The puncture hole will

assume a longitudinal or transverse closure or a hybrid of both. The stapling device, following advancement over a guidewire, has the ability to release one or more of the staples in parallel from the nose of the delivery device, at the end of the firing cycle. Also, the ability may exist to mechanically maintain each step in the firing cycle in a fixed position until further pressure is applied on trigger. This ensures smooth and controlled delivery of staples to margins of puncture site and should result in satisfactory closure of same. The stapler may be withdrawn along the guide wire (if still in place) once trigger mechanism has been totally closed and subsequently released. Finally, the guide (if still in place) is removed and the tract inspected for bleeding. A sterile dressing is then applied and the patient is observed for a predetermined time before ambulation and discharge.

What is Claimed is:

Claim 1

A method for arresting the flow of blood from a blood vessel puncture site by stapling means after completion of a percutaneous medical procedure where said procedure results in the insertion of a sheath along a guide wire or other guiding mechanism into the lumen of the patient's blood vessel through a puncture in the patient's skin and through the underlying subcutaneous tissue into the blood vessel.

Said method comprises insertion of a guide wire or other guiding mechanism into the blood vessel through existing sheath at end of diagnostic or interventional procedure, passing a dilator with hollow channel throughout its length over said guide wire through the percutaneous tract and underlying subcutaneous tissue onto the outer surface of the blood vessel. The site of the dilator may be confirmed by advancing a fine bore tube through the lumen of the dilator over the guidewire and into the blood vessel for a fixed distance as indicated by graduated markers which may be present on both dilator and plastic tubing and may also be facilitated by radio opaque markers, which may be seen on radiological screening.

Following removal of said dilator and plastic tubing but leaving guide in place, the free end of guide emerging from skin tract is advanced through channel running along shaft of a new surgical stapling device, said surgical stapling device is advanced along the guide wire through the skin and underlying tissue onto the surface of the blood vessel. Localisation of distal end of stapler in relation to puncture site may be facilitated by graduated markings on side of stapler shaft. Position may be confirmed by advancing inner plastic tubing along shaft of stapler on guide wire and into the puncture site. Tubing may be advanced into the blood vessel lumen for fixed length, and exact position of distal end of stapler with relation to outer surface of blood vessel may be confirmed by observing the backflow of blood. The ability exists to perform angiogram through plastic tubing if

required. Following confirmation of the stapler position, the tubing may be pulled back along the guide wire into the shaft of the stapler. The pulsation of blood then ceases. At this point the distal of the stapler which is orientated by the guidewire is now placed firmly against the blood vessel wall.

On retracting plastic tubing into shaft of stapler, deployment of the staple or staples is initiated simultaneously and in parallel (if more than one staple is deployed), the ability may exist to observe indirectly the deformation phase of the staples on a diagramatic marker within handle or body of stapler. The ability also exists to observe protrusion of vertical legs of each staple on radiological screening if required. The ability also exists to inject contrast medium around surface of blood vessel to confirm positioning if required. Further activation of the staple delivery-mechanism results in advancing the staple or staples of pre-determined shape by staple former onto pre-determined shaped anvil. At any stage the guide wire may be removed from the blood vessel, even before staples have engaged in outer surface of arterial wall.

The closure mechanism of staples is completed by advancing the staple former which forces the staple or staples into the arterial wall with the guide wire still in place. Deformation of the staple or staples to a predetermined shape is achieved by deforming the staple or staples over an anvil or anvils of predetermined shape which is located in the distal end of the stapler. As the staple pierces the blood vessel it will cause the opposite sides of puncture hole to approximate. The puncture hole will assume a longitudinal or transverse closure or a hybrid of both. The stapling device, following advancement over a guidewire, has the ability to release one or more of the staples in parallel from its distal end at the end of the firing cycle. Also, the ability may exist to mechanically maintain each step in the firing cycle in a fixed position until further pressure is applied on trigger. This ensures smooth and controlled delivery of staples to margins of puncture site and should result in satisfactory closure of same. The stapler may be withdrawn along the guide wire (if still in place) once trigger mechanism has been totally closed.

Finally, the guide (if still in place) is removed and the tract inspected for bleeding. A sterile dressing is then applied and the patient is observed for a predetermined time before ambulation and discharge.

Claim 2

A mechanical stapling device with one or more staples mounted in the distal end. This device has one or more purposely built hollow channels running along its shaft which can accomodate a guidewire and therefore has the ability to be advanced over a guide running through one of these purposely built channels. This guide will have been previously been placed percutaneously into the lumen of a blood vessel and brought to the outer surface of the blood vessel puncture site without direct visualization of the puncture site. Localization of the site of the distal end of the stapler with respect to the puncture site without direct visualisation of its position may be confirmed by advancing blood vessel locator tubing (which passes from proximal stapler shaft, along length of shaft and exits at distal end of shaft in front of , or behind staple (or staples) or between first and second staples) over guide (running in purposely built channel) and into blood vessel puncture site for predetermined distance. Backflow of blood through the locator tubing is taken as confirmation of site of distal end of stapler. Staples may now be deployed about guidewire and tubing (if so desired) to effect closure of puncture site.

Claim 3.

A method whereby after positioning of the stapler as in **Claim 1**, the guide is removed prior to deployment of the staples to effect closure of the puncture site.

Claim 4

A device as in **Claim 2** for closing a puncture hole in the blood vessel by means of a mechanical stapling device placed over a guide (metal wire, plastic wire, hollow tube or other guide means), and after localizing the position of the stapler using blood vessel puncture site locating tubing, delivering one more metal or absorbable

or nonabsorbable implantable staples comprising of sharpened legs and transverse bar, into the margins of wall of the puncture hole in blood vessel with the end result that the opposite walls of the blood vessel puncture site are approximated. The staples are deployed at a pre-determined lateral distance from the outer circumference of the guide.

Claim 5

Device as in **Claim 2**, where the device has the ability to deploy one or more staples either simultaneously or seperately. Activation of the staple deployment and deformation mechanism of the stapler results in one, two or more staples passing through the outer wall of the blood vessel either simultaneously or in a predetermined sequence deforming in such a manner as to deflect the pointed legs of the staples towards each other resulting in shortening of height and width of staple or staples deployed and causing the opposite margins of the blood vessel wall around the puncture to be approximated. Staples will then be released from the stapling device allowing its removal and also removal of the guide if the operator has not already done so.

Claim 6

Stapler as described in **Claim 2** with a hollow channel or channels along the length of shaft allowing for the stapling device to be advanced over a guide to an anatomical site which if not visible to the eye, may be indirectly located using radiological screening means. This hollow channel or channels may also accomodate a blood vessel locator tube which may be advanced over the guide or advanced in isolation into the blood vessel puncture site via seperate channel running through shaft of stapler. Backflow of blood indicates position of stapler in relation to puncture site.

Claim 7

As in **Claim 6** whereby an angiogram may be performed through this tubing to further confirm position of stapler or alternatively medicated solution may be injected through this tubing if so required.

Claim 8

As in **Claim 1**, whereby the shaft of stapler may act as its own dilator of tissue tract because shaft of stapler has required profile for this function. Furthermore, the hollow channel (or channels) passing along its length facilitate guide mechanism and blood vessel locator tubing.

Claim 9

A device as in **Claim 2** whereby if the shaft of the stapling device is brought towards perpendicular position in relation to the skin, it will result in the guidewire assuming an angle approaching or greater than 90 Degrees and this may cause the puncture hole to be stretched and to change from a roundlike shape to resemble more a verticle opening and therefore has the effect of bringing the opposite walls closer together.

The Patent Office

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Application No: GB 9621622.1 **Examiner:** Mr S J Pilling
Claims searched: - **Date of search:** 10 January 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RESB, RESC, RESX, REL)

Int Cl (Ed.6): A61B 17/068, 17/072, 17/115

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	WO 94/21181 A1	(BAUDET) 29.09.94 (see the figures, and also WPI Abstract Accession No. 94-304852/38)	-
A	US 4493322	(BECHT) see the abstract and the figures.	-

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.